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LUKAS HERMANN BENJAMIN TIETZ

DEVELOPMENT OF AN ARCHITECTURE FOR A TELE-MEDICINE-BASED LONGTERM MONITORING SYSTEM

Master of Science Thesis

Examiner: Prof. Jari Viik and Prof. Jukka Vanhala
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ABSTRACT

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Every day gigantic amounts of digital data are produced by billions of devices around the globe. Using this kind of data and develop applications of unlimited possibilities have created the Internet of Things (IoT) idea. Furthermore, wearable devices have taken up the recognition not only for private users, but also medical device producers and start-up companies. They have realized the potential of wearables in medical applications and their importance for the future of tele-medical systems, when being combined with an IoT based architecture. Despite the development of recent tele-medicine platforms, none has used printed electronics to obtain physiological signals.

This thesis will provide a description of an architecture, that not only uses an IoT application as backbone, but also a hybrid printed electronics design for ECG and Bioimpedance Pneumography measurements. The recorded bio-signals are transfered via Bluetooth Low Energy to a mobile gateway and then onto a server. On the server the data will be processed in order to obtain features of each signal that provide significant information about the patient's health. Finally this data is stored in a backup system and can be viewed through a graphical user interface.

As this thesis is rather a literature review than an experimental work, there will be no methods segment. An extensive background with the state-of-the-art technologies will be provided. The description of the architecture, shows that all the principal layers of an IoT application are met. Issues that arise with the usage of these systems are critically evaluated. This is the basis for researchers in the DISSE (DISappering SEnsors) project, in order to enable them to see the overall picture around their work within the project.

PREFACE

This thesis was done at the Tampere University of Technology (TUT), in the department of Electronics and Communications Engineering in 2016. The design for the architecture was part of the Disappearing Sensors project, shortly DISSE project, funded by TEKES.

I would like to thank my supervisor Professor Jari Viik for giving me this opportunity. I am grateful for his patience during the time it took to finalize the thesis and for his guidance and advice given for the research and thesis. I would also like to thank the whole DISSE research group for providing an inspiring and communicative working environment.

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Tampere, 15.5.2016

Lukas H. B. Tietz

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LIST OF ABBREVIATIONS

2G	2nd Generation mobile Networks
3G	3rd Generation mobile Networks
4G	4th Generation digital cellular Networks
ADAMM	Automated Device For Asthma Monitoring And Management
BI	Biological Impedance
BIA	Bioimpedance Analysis
Bio-signal	Biological Signal
BIP	Biological Impedance Pneumography
BLE	Bluetooth Low Energy
BR	Basic Rate
BSS	Base Station Subsystem
BT	Bluetooth
DISSE	Disappearing Sensors project
DVB-T	Digital Video Broadcasting - Terrestrial
ECG	Electrocardiography
EDR	Enhanced Data Rate
EIP	Electrical Impedance Pneumography
ETSI	European Telecommunications Standards Institute
eHealth	electronic Health
FDA	United States Food and Drug Administration
GAO	Government Accountability Office
GATT	Generic Attribute
GPRS	General Packet Radio Services
GPS	Global Positioning System
GSM	Groupe Spécial Mobile, Global System for Mobile Communications
GUI	Graphical User Interface
HL7	Health Level 7
IEC	International Electrotechnical Committee
IoT	Internet of Things
IoT GSI	Global Standards Initiative on Internet of Things
IoE	Internet of Everything
ITU	International Telecommunication Union
LTE	Long Term Evolution

mHealth	mobile Health
NFC	Near Field Communication
PAN	Personal Area Network
SIDG	Bluetooth Special Interest Group
SMS	Short Message Service
TPU	Thermoplastic Polyurethane
UMTS	Universal Mobile Telecommunications Service
WLAN	Wireless Local Area Network

1. INTRODUCTION

The development of using smart devices in everyday life has lead to a revolution of internet capable devices. Smart phones, smart watches, activity trackers and other wearable devices are connected to each other and the omnipresent internet. Today, every second more than 28875 Gigabytes of data are created and a large part of it is uploaded into the internet and by 2018 this number is estimated to be almost doubled [1]. With the increasing sells of fitness and mobile health (mHealth) devices the part of this data that represents medical data is increasing daily. The trend for performing self-control, or personal health is continuing. This also supports the research in wearable technology that can record and assess medical data, which exceeds step counts and heart rate determination. Currently, more than 100000 mobile applications that deal with health or medical background are available for smartphones [1]. Whole wearable electrocardiography and blood pressure measurement devices are now in development [2]. With this research not only the private customers profit, but also the medical sector can improve its' capabilities: remote monitoring systems are an idea already from the 1960s, but enabled through permanently online smart devices and wireless technology telemedical homecare or healthcare systems are closer to publication than ever. The Internet of Things (IoT) or Internet of Everything (IoE) ideas are right now dictating the developments in mobile and digital sectors [3].

It is a challenge to develop a modular and expandable tele-medical systems, and, although, medical device producing companies are offering their in-house and complete solutions, they are ofter very expensive or incompatible with other, existing systems. This makes a market introduction merely impossible as hospitals or other healthcare providers often cannot make an investment into a system that is not compatible with their already existing ones.

Another issue with already presented telemedical architectures is that they often rely on wired technology and then the collected data is transfered onto a server, where medical professionals can retrieve the data important for diagnostics. Even novel designs are still relying on the usage of cables, as [2] shows. To provide a truly innovative and forward-thinking telemedical architecture, one has to consider also new technologies: Stretchable printed, ultra-light electronics and an Internet of Things based approach can enable a true wireless system. Integrating electronic structures in clothing that then are connected to a internet-capable device is a fairly new idea and a good start for thinking about integration of new technologies in a tele-medical application.

The goal of this thesis is to describe such an architecture and to evaluate its impact onto the future of tele-medical systems. A complete basis for the development of the individual parts and their combination will be provided. All pieces will be described individually to enable the researchers of the Disappearing Sensors (DISSE) TEKES-project, of which this work is a part, to combine their individual systems to one working proof-of-concept prototype system. This will be tested in the facilities of Koukkuniemi Home for the Elderly in Tampere, Finland.

The architecture will incorporate a wearable piece of clothing in form of a T-shirt provided by Clothing+, in which screen-printed, strechable electronics are laminated. Rigid electronic units attached to the stretchable substrate are enabling Electrocardiography and Electrical Impedance Pneumography, as well as wireless communication via Blutooth Low-Energy to a mobile reciever. From this gateway smart phone, which is provided by Elisa Oy, data is transfered via a mobile internet connection that is based on Global System for Mobile Communications (GSM) to a Finnish located server, on which the data is processed and stored. Finally, users can access the data via a graphical interface and through different profiles that allow different levels of access.

In Chapter 2 of this thesis, the background for this work is covered, by briefly taking a look at the important bio-signals and their measurements, then wireless communications that are important for tele-medical applications, lastly the Internet of Things idea is also examined, together with challenges for biosecurity and the standardization of medical records. In Chapter 3 the architecture will be described in its three main parts: the patient site, the server site and the user site. The Discussion, Chapter 4, will cover the flaws of this design and suggestions for the possible and necessary enhancements are made. Chapter 5 concludes this work.

2. BACKGROUND

2.1 Tele-Medicine and Monitoring

Over the course of more than 40 years tele-medicine has developed rapidly. Being defined as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status" [1] [4]. The focus mainly lays on giving patients remotely the assistance to treat their (chronic) conditions [5]. The usage of telemedical systems should decrease the number of longterm hospitalized patients and, therefore, the costs for any medical institution with patient beds. Also, increasing the patients' comfort who can recover either at his own home or any other familiar environment and decreasing the need for frequent visits at the hospital [6]. Furthermore, medical or healthcare information systems will support clinical decision making in the future [7].

The development of more capable hard- and software enable more complex services to be included into tele-medicial applications. Faster microprocessors make it possible to create real-time analysis of the patient status, utilizing compilation methods of several measurement devices. Smartphones and webcams enable face-to-face-video doctor-patient-interaction. Smaller medical devices do their part for making physiological measurements portable. Over the years, multiple attempts have been made to exploit different infrastructures, in order to make remote medical access possible, e.g. the DVB-T approach from 2008 in [6]. Still, mainly inter- and intranet-based technologies are the ones that will lead the market [8, 9].

A modern approach to a tele-medical system is shown by Wang in [10]. A complete system is described, which consists of medical devices that are linked wireless to receivers and those are connected to a server. On the server a medical record database is located, as well as decision supporting and data processing algorithms

[1] American Telemedicine Association. 'What is Telemedicine?', 2012. [Online]. Available: http://www.americantelemed.org/about-telemedicine/what-is-telemedicine.Vwz46mNQ5SU. [Accessed 12- Feb- 2016]

are run. Medical Staff as well as the patient shall be able to access recorded data via an interface. All connections are secured with state-of-the-art encryption. As the system is proposed to be applied in the whole country of Taiwan, standardization suggestions for the medical records are also proposed. In figure 2.1 an overview of the systems schematics is shown.

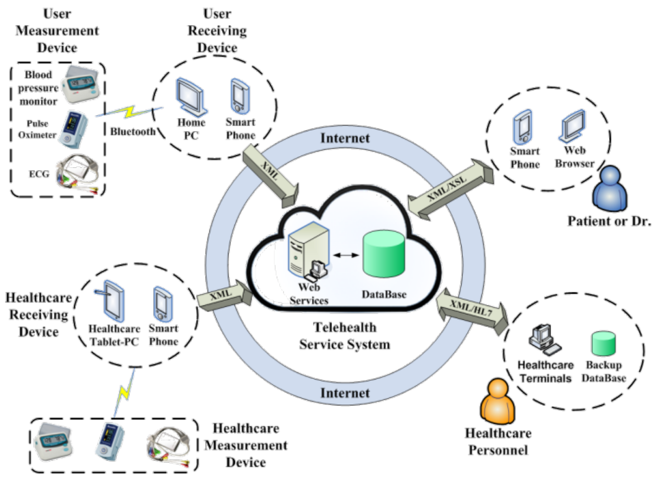

Figure 2.1 *A TeleHealthcare system consists of different parts and grants access to user groups. Central to most modern Telemedical systems is a server, which stores and manages digital data [10].*

The development of high-speed mobile data connections, like Fourth Generation digital cellular Networks (4G) and Long Term Evolution (LTE, see chapter 2.1.2), in latter years now enable even more applications. An ECG measurement recorded on a smart phone and sent to the hospital in advance, can reduce the decision-making time for cardiologists and cardiac patients by a significant amount of important time. The doctor can already make decisions on the status before the patient is even at the medical institution. Mobile devices will therefore play an; if not the most; important role in the devolpment of future tele-medical systems, this is the so-called mobile or electronic health (mHealth or eHealth) movement [11].

In the following sections the basic topics for a tele-medicine system will be explained in more detail; starting with the biological signals and their measurements that are important for this thesis: Electrocardiography and Electrical Impedance Pneumography. Followed by the wireless connection standards: Bluetooth Low-Energy and mobile data connections (GSM, 3G and 4G/LTE), which shall be taken advantage of in the connectivity of the, in chapter 3, described architecture.

2.1.1 Bio-Signal Measurements

Bio-Signals

Biological signals (bio-signals) are phenomena that are used to describe the functional state and the change of state of a living organism or parts thereof. They provide information on metabolic, morphological and functional changes, describe physiological and pathophysiological states, and the dynamics of processes. For their analysis, the origin and, thus, the spatial and temporal allocation is important. They are obtained from living organisms, organs and -parts or individual cells. Basically two categories can be distinguished: deterministic and stochastic bio-signals [12, 13].

Electrocardiography - ECG

Electrocardiography (ECG) has not significantly changed over the course of the last few decades. The basic Einthoven-three-lead, or bipolar acquisition, as well as the extended 12 lead method techniques are still clinical standard. Utilizing 10 electrodes that are placed on the subjects body, this is the most important non-invasive (cardiac) diagnosis supporting test. The resulting ECG waveform is the representation of the heart muscles' combined electrical activity during different time points of a heart beat. A healthy person is classified with a constant rhythmic 60-75 R-peaks or beats-per-minute ECG. The R-peak marks the highest amplitude in an ECG wave of one heart beat [14, 15].

Different durations of ECG can support the diagnosis of chronic or acute diseases. Short term measurements are usually used for a general assessment, whereas long term recordings are carried out if a chronic suffering is suspected. What all, of the nowadays made recordings, have in common is that they are recorded digitally. The electrical signal is lead via the electrodes and leads towards the electro-cardiograph. After analog-digital conversion and filtering, the signal is usually displayed at a screen and, basically always, stored in the devices own memory for later access. However, over the course of recent years the digital recording has brought significant changes into how the data of ECG measurements is stored. In the literature 39 different digital formats have been reported, originating from the manufacturers or standardization organizations like Healthlevel 7 (HL7), The United States Food and Drug Association (FDA) or the International Electrotechnical Committee (IEC)

[16].

Electrical Impedance Pneumography - EIP

Biological Impedance (Bio-Impedance), or the resistance of tissue, has multiple applications. The most common one nowadays is found in body composition measurements, named bio-impedance analysis (BIA), where the percentage body fat compared to muscle and other tissues is determined [17]. Utilizing basically the same principle of feeding a high frequency, low current electrical voltage via two electrodes to the body and measuring the impedance between two different electrodes, is also the electrical impedance pneumography (EIP) [18].

EIP is used to determine the breathing frequency. The impedance changes with the breathing process. While breathing in the impedance is increasing and vice versa. the alternating impedance is measured with two or four electrodes placed on the side of the chest (see figure 2.2). The recorded signal is of deterministic character, which makes it easy to determine certain features out of it [19].

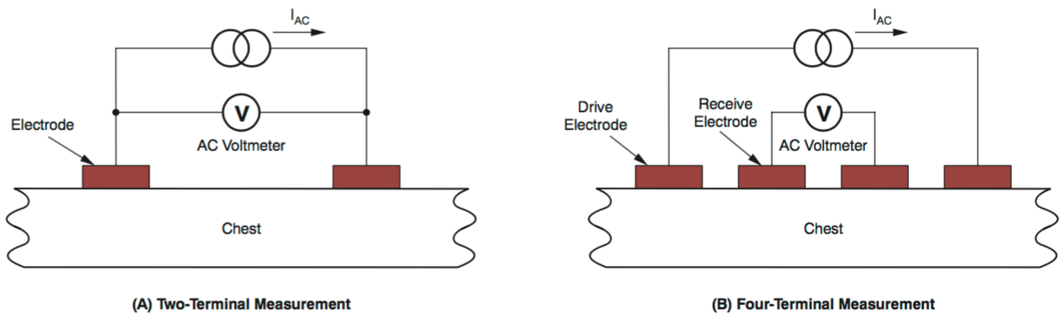

Figure 2.2 *Impedance Pneumography is carried out in two configurations: A) with two electrodes and B) with four electrodes [20].*

Current Technologies have not much changed since the 1990s. The technique however is still widely and commonly used [20].

Printable Strechable Electronics

Measurements relying on conductive methods are usually done with electrodes attached to the body's surface. Self-adhesive electrodes ensure skin contact and a small transition resistance, which is needed for accurate measurements [13]. However, skin attached electrodes have the disadvantage in various situations during daily life. Therefore, another method has to be applied when conducting long term measurements. Not only the electrodes do have an impact on daily life, but also the leads, that transport the electrical current from the electrode towards the measuring element. They have to be affixed to the body with plasters or similar, in order to not hinder the patient.

ECG and Bio-Impedance measurements, both rely on conductive contact to the patients' skin. To avoid having to use cables for conduction, printable and stretchable leads and electrodes have been introduced. These components can be produced together in one step. There are different methods of printing these structures, as well divers materials can be used [21]. It has to be mentioned that not only the ink is the stretchable part in the applications, but also the underlying substrate. In most cases this is a flexible Thermoplastic Polyurethane (TPU) sheet, on which the conductive ink is printed on.

Utilizing screen printing, a technique where the desired image is masked on a mesh, with impermeable areas around it, and the ink is transfered through said mesh onto a substrate [22]. Especially for stretchable electronics this very old technique is favored, since the deposition of ink can be done with high control [23]. The process is depicted in figure 2.3, showing the three steps of ink depositing through a mesh grid onto a substrate [24].

Using a conductive ink instead of regular ink, one can print structures onto the substrate that are acting as a electrical circuit. Those flexible circuit boards can include structures, where solid electronic components can be mounted using certain techniques, for example gluing them on, using conductive glue. Those combinated structures are called hybrid systems [23].

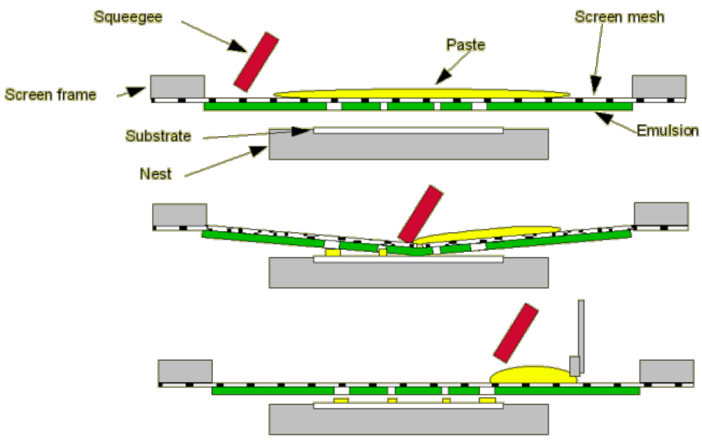

***Figure* 2.3** *The principle of the screen-printing process [24].*

2.1.2 Wireless Communication

Bluetooth/Bluetooth Low Energy - BT/BLE

Bluetooth (BT) technology is a global wireless standard for short-range, packet based communication. It was introduce in 1994 and intended as replacement for cable connections. BT utilizes radio transmission to send data between devices equipped with an appropriate module. Designed to be an open standard, Bluetooth enables connectivity and collaboration between different devices, brands, even industries. The worldwide spread of this technology, basically makes it the enabler of IoT technology. Lately, medical devices also have been equipped with BT radios to be able to communicate wireless. Nowadays, the most common application for BT are wireless headphones or speakers, such as in hands free car accessories [25]. Generally, there are three different types of Bluetooth connections:

1. Bluetooth Basic Rate (BR)
2. Bluetooth Enhanced Data Rate (EDR)
3. Bluetooth with Low Energy Functionality (BLE)

While the first two types are commonly used in larger electronic devices, e.g. wireless headsets or printers; Bluetooth Low-Energy, or so called Bluetooth Smart®, is utilized in micro sensor systems or smart devices. Later in this section BLE will be discussed in more detail. All these types, however, operate in the same unlicensed industrial, scientific and medical (ISM) band at 2.4 to 2.485 GHz, to ensure no interferences with other wireless communications like Wireless Local Area Network (WLAN) or Global System for Mobile Communications (GSM) [26].

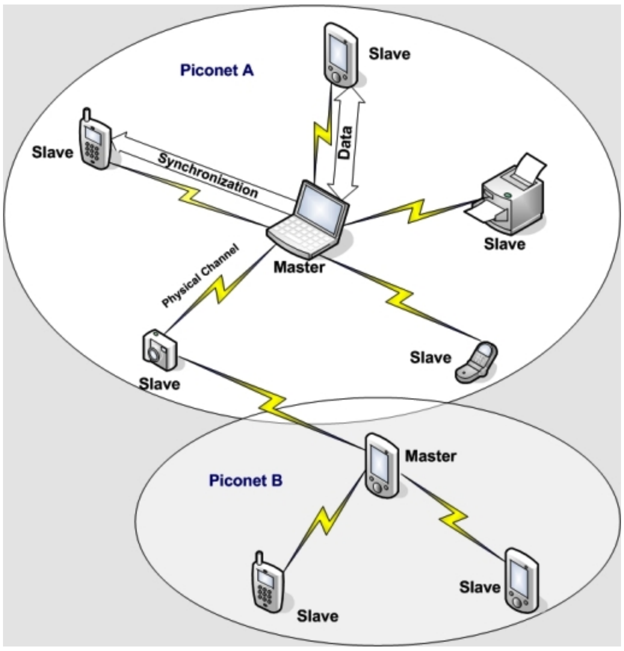

***Figure** 2.4 The principle of Bluetooth connections [27].*

Bluetooth enabled devices connect between a Master device and a Slave device. Thereby, a master can have up to 7 slave devices connected to it in a Personal Area Network (PAN), the so called piconet environment. In figure 2.4 The connection principle is shown. It is also depicted that a slave device can be a connected (paired) to multiple master devices [27].

Each device has its own, unique 48 bit address. In order to connect two devices the following steps are either done automatically or manually, if the connection is made for the first time [27]:

1. Device A is activated and searches for available connections
2. Device B is found, the pairing process is started

3. Pairing process: the identities of both devices are exchanged
4. The pairing is finished
5. A Personal Area Network (PAN) is formed
6. The connection is operable

Bluetooth Low-Energy Modern Bluetooth devices that are classified as Bluetooth Low-Energy or Bluetooth Smart® are more power efficient than earlier versions. This standard is applied to many devices since 2010, and was originally introduced as Wibree by Nokia in 2006. The technology now enables developers to create systems that include sensors, microprocessors and a Bluetooth Low-Energy module, which are powered by not more than a single coin battery. Power harnessing techniques might even provide a longer lifetime to those systems, if not unlimited life. This already is applied in wearable technologies, where small batteries power the devices multiple days or weeks with a single charge, despite a permanent bluetooth connection with a mobile phone [25].

While BR and EDR rely on determined profiles and protocolls, BLE was developed on the basis of a development framework that utilizes Generic Attribute (GATT) [25]. These attributes are used by the developers to build so called profiles. The GATT can be assigned and determine which information is sent during a connection process, or which services can be used by the connection partners. With this, basically any device can be equipped with a bluetooth module and, the correctly built profile presumed, will be able to communicate with any other device that supports the standard. A number of basic profiles and services that utilize GATT is available on the web page of the Bluetooth Special Interest Group (SIG) [28].

GSM/3G/4G mobile Networks

This section will give a closer insight into mobile cellular networks. The communication via Global System for Mobile Communications (GSM), third generation cellular networks (3G) and fourth generation digital cellular networks (4G) works via local radio antennas. Each antenna forms a cell around itself, hence the name cellular networks. According to different standards a mobile telephone is communicating with those local receivers on certain frequencies, which are required by each standard. These antennas are called Base Station Subsystems (BSS) and are run by the base station controller which itself redirects the requests from the Mobile Equipment either for telephone services or for internet services towards the appropriate direction. Figure 2.5 depicts the basic structure of a GSM network. All newer mobile cellular networks share the same basic principle [29].

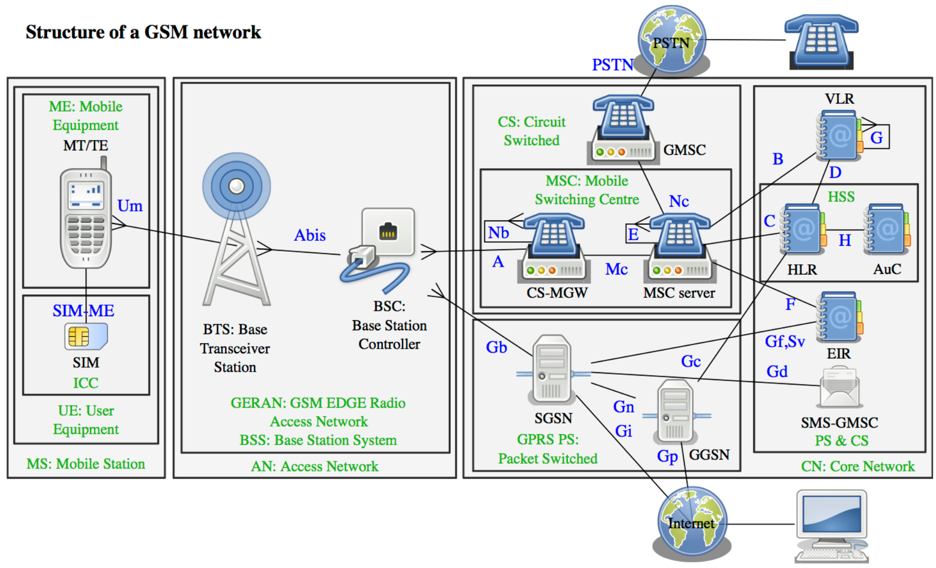

Figure 2.5 *The structure of a GSM network consists, simplified, out of the Mobile Equipment, the Base Station System and the appropriate Core networks for internet or telephone functionality [29].*

Global System for Mobile Communications (originally Groupe Spécial Mobile, GSM), is an international standard developed in 1989 by the European Telecommunications Standards Institute (ETSI) for the description of protocols for second-generation (2G) digital cellular networks. As Finland was leader in mobile phone coverage, this technology was first deployed in 1991 there [30]. Except in Japan and both Koreas GSM is the worldwide standard and operates on either 850, 900, 1800 or 1900 MHz in more than 219 countries and territories [31].

GSM also introduced the packet data transport via General Packet Radio Services (GPRS) in 1995, which was the first mobile data connection. GPRS enables e.g. Short Messages Service (SMS). The data connection is limited to a download speed of 64.2 kBit/s and an upload speed of 42.8 kBit/s [30].

A further development of this standard under ETSI is the third generation of mobile telecommunications technology (3G). The third generation was introduced in

1998 and required providers to offer a download speed of maximum 200 kBit/s.[30] The Universal Mobile Telecommunications Service (UMTS) system enabled mobile internet connections and, other than 2G, is transmitted on the 2100 MHz frequency [31].

The Fourth Generation digital cellular Networks (4G), or often referred to as Long Term Evolution (LTE) is the current generation of cellular networks. Unlike it predecessors, 4G is defined by the International Telecommunication Union (ITU) and was introduced in 2008. High speed mobile connections are possible with speeds of up to 1000 MBit/s (only in true LTE), and enable data intensive services like video streaming and fast internet access [32].

These digital cellular networks, build a base for the communication between a smart phone and the internet, which makes them the backbone of the Internet of Things technology. Later this technology is described in more detail and it is shown how the devices are working together.

2.2 Wearable Technology

Wearable devices are ny sensor bearing device that can be worn by the user, which is connected to a smart device of some sort. The most common ones are battery powered activity trackers or sport watches. The biggest challenge in the design of such a device is the size and its' unobtrusiveness for the wearer. They have to be small, light and comfortable to wear. A wireless connection is also necessary, in order to keep the practicability high. The materials have to be bio-compatible and bioinert at the same time. The incorporated electronics also have to be minimized in order to achieve the mentioned properties [33].

2.2.1 The Self Control Movement

As indication to the wearables' increasing significance might the example of the self-control movement the most important. In latest years personal tracked fitness became more important and with the available microfabrication methods sensors became smaller and, therefore, could be implemented into devices that are small enough to be worn without a large distraction; 'Wearables' were born. This movement is also called personal health or mobile health (mHealth), as most of the available devices are to be connected with a smart phone of some sort. The wearable devices produce a vast amount of information every day, this data can, correctly treated, support the diagnostic power for patients of any kind. Users of activity trackers state that the living with these wearables has a positive effect on health choices and also a positive effect on the amount of movement during the daily routine [1].

The most important 'wearables' to be mentioned are the armbands, that give the user control over different functions as well as the possibility to track the daily movement profiles or, in special hardware, the heart rate at any given moment. Other functionalities, like sleep quality measurement and position tracking via Global Positioning System (GPS) are available depending on price of the device and the respective manufacturer. So called smart watches not only have the tracking functionalities, but also offer the control of the smart phone itself and other third party application interactions directly on the wrist worn device [34]. Normally, the devices connect to the smart phone and require the corresponding application, to be able to transfer the recorded data.

The biggest companies in wearable technologies are Apple, Fitbit and Google with their respective devices: Apple Watch, Fitbit Charge and Android Wear. And the market for these wearable devices is still growing, given the 168 % growth of the Fitbit Inc. in 2015 [34]. The Finnish company Polar Electro also offers a wide range of different devices, from simple step counters to a high-end gadget the Polar V800, that offers continuous hear rate monitoring and GPS functionality, next to being waterproof and smart phone control for about 400 €[35].

The self control movement is driven by the willingness to increase one's personal health by increasing the daily activity and adjust it towards a more healthy lifestyle. Thereby, also calorie intake and weight can be tracked. With the option between the different trackers one can additionally, automatically measure more signals. The product palette of Fitbit Inc. shows the different types of trackers available from most companies in the market (see figure 2.6). Starting with a simple step counter, the Zip, over the Charge, that also offers sleep analysis, to the higher-middle class devices called Charge HR and Blaze, which offer continuous heart rate monitoring. The best available device from Fitbit is the Surge, which also allows smart phone control and GPS based location tracking [36]. Next to the wearable tracking devices, many companies started to offer smart scales that also connect via Bluetooth Smart® to one's smartphone.

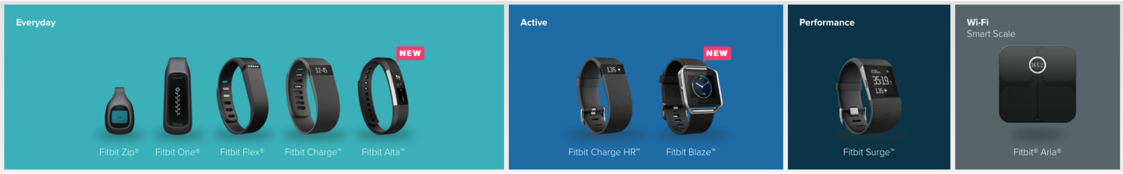

Figure 2.6 *The Fitbit Product Palette starts from simple stepcounters and offers also high-end devices with heart rate monitoring and GPS tracking [36].*

The mentioned smart scales often also offer body composition measurement, that are done by the earlier described bioimpedance analysis. The choice for using self control, that is supported by smart devices often starts with the choice to start a healthier life style, which means: more movement, loosing weight and eating healthier. Lots of supporting smart phone applications not only connect with a fitness tracker but also provide the feature of tracking energy (calorie) intake and food lists, and then give actively meal suggestions [36].

2.2.2 'Wearables' in Medical Applications

The trend to use small devices that are connected to a smart phone is not limited to the private sector. Medical companies also start offering devices that work independently with their own applications; The General Electric (GE) Healthcare division also released an article quoting a video by The New Economy, that wearables will change the landscape of healthcare and that GE is also addressing the two general key of implementing networking between devices and miniaturization of sensing devices [37].

But not only the 'global player' GE is developing in that direction, also smaller companies start selling devices with a defined healthcare background. This, potentially, can result in a more personalized treatment for any patient that uses such devices and shares the outcomes of measurements with medical professionals. Wearables can help controlling the movement during exercise to provide feedback, whether the execution was correct or not. But also other applications can be realized as the following examples of wearable devices, which support of medical treatments and diagnosis, show [38].

The Valedo Back Therapy is a wearable position observing sensor, that is aimed to help patients with lower back aches. Reminders for desk workers to stretch their back once in a while as well as games and suggestions for lower back exercising are included in the companion application for smart phones [38].

The Quell Relief is an electrical stimulator that is targeted to chronic pain patients. It is a knee brace for support of movement. Implemented is an electrode that stimulated the underlying nerves for pain relief on the press of a button. Again, accessible through a companion app is the interface that provides statistics about the usage of the device and the quality of sleep [38].

The Automated Device For Asthma Monitoring And Management (ADAMM) by Health Care Originals provides real time respiratory monitoring for asthma patients. The product is currently under development and is expected to alert the users when an asthmatic situation happens. As well journaling, tracking of situations and treatment plans can be displayed in the application. The device is worn on the chest (see figure 2.7) and connects to the smart phone via Bluetooth [38, 39].

Figure 2.7 *The Automated Device For Asthma Monitoring And Management (ADAMM) by Health Care Originals provides real time monitoring for asthma patients [39].*

Targeted on patients that have to use medications regularly is the Helius a swallowed pill by Proteus Digital Health. The ingestible sensor is taken along side the other medications and is sending a signal at the time of ingestion to the worn patch called Discover, which provides the basic information about the patients health in form of heart rate measurements, step counting and blood pressure. The resulting data shows the medical professional whether the patient is taking the prescribed medicines correctly and what effect those have on the body [38].

A recently intensively studied subject is the early diagnosis of cancer. Breast cancer is the second most lethal type of cancer for women, therefore, regular check ups are suggested by medical professionals. A supporting wearable device is the iTBra by Cyrcadia Health, that tracks conditions and rhythms in the breast tissue and alerts the user of a possible case of breast cancer. The accompanying application gives insights on recorded data and provides information about optimal breast health.[38]

2.3 Internet of Things

2.3.1 The IoT Idea

With more advanced technologies, such as high speed mobile connections and low power short range connections, as the ones described above, new ways to connect devices to each other were found. The most prominent one right now is Internet of Things, where the data that is produced by the vast amount of devices, is used for actuator control, process analysis and other applications. The standardization of IoT is run by the Global Standards Initiative on Internet of Things (IoT-GSI).

The Internet of Things (IoT) is the network of physical objects/devices, vehicles, buildings and other items embedded with electronics, software, sensors, and network connectivity that enables these objects to collect and exchange data. The Internet of Things allows objects to be sensed and controlled remotely across existing network infrastructure, creating opportunities for more direct integration of the physical world into computer-based systems, and resulting in improved efficiency, accuracy and economic benefit. Experts estimate that the IoT will consist of almost 50 billion objects by 2020. Cisco showed a reference IoT architecture model, showing all layers of a IoT application. The schematics in figure 2.8 show the seven general layers of a structure [40].

These seven general layers are, described from the bottom to top, are shown in Table 2.1 [40].

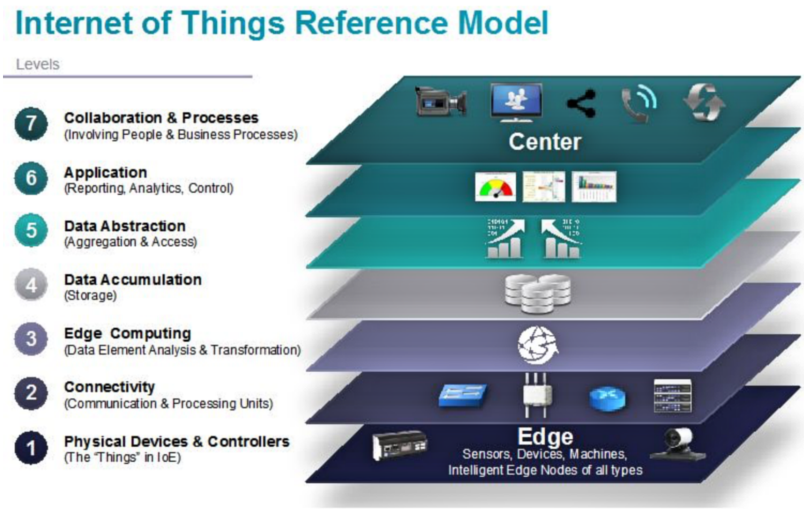

Figure 2.8 *The visual representation of Internet of Things Model shows 7 layers, from 1) the physical layer to 7) human interactive collaborations and processes [40].*

Table 2.1 *The IoT Layer Structure according to Cisco Systems, Inc. [40].*

Layer	Cisco Systems Description
Layer 1	Physical Devices & Controllers
Layer 2	Connectivity
Layer 3	Edge Computing
Layer 4	Data Accumulation
Layer 5	Data Abstraction
Layer 6	Application
Layer 7	Collaboration & Processes

Starting at the physical layer, means the physical sensors and actors in an IoT application. Taking a simple example in consideration, remotely controlled agricultural watering, the physical layer is represented by sensors for temperature and air humidity. As this layer also describes the applications' actors one has to mention the valves for the watering lines to the fields, that can open and close, according to need.

The second layer of an IoT application is represented by the connectivity, i.e. how the sensors provide their collected data to the operation. In the case of the automated watering system, this is usually done via a GPRS module attached to the sensors, which directly transfers the data into the internet. In other applications close range communication towards an internet capable device are possible, e.g. a Bluetooth connection to a mobile phone.

The mentioned GPRS module in the example application also introduces the third layer: Edge Computing. The collected data is transformed into data packages of chosen sizes and sent into the internet, that usually is presented through a server of some sort.

Layer four: The data accumulation is the mentioned server, the incoming data from the GPRS module is unpacked and stored in the intended format for further use. The temperature and humidity, as well as the status of the valves are stored in an database table. Also, the average values of temperature and humidity are calculated and stored.

In the data abstraction step, the collected and stored data is processed for the intended use in the application. In case of the watering system, the application runs database queries to receive the values for temperature, humidity and valve statuses.

The application layer of an IoT architecture is usually represented by a user interface, that allows interaction. The requested values for temperature, humidity and valve statuses are presented in a graphical user interface (GUI) and the user can interact. For example see the trend report of the average temperature over the past 7 days, or control (i.e. open and close) valves with a mouse click or finger tap.

The last layer, which is collaboration and processes, involves usually interaction between humans utilizing the same architecture. As the watering system is intended for one farm to use there is no representation of the example for this layer. However, thinking of a telemedical application of an IoT system, video calls between doctor and patient can be mentioned. As well, the triggering of an alarm, due to certain circumstances, is to be named as collaboration.

Viewing the roadmap (figure 2.9) for the IoT technology from 2008, one can recognize that most of the goals that were anticipated till 2020 are already realized and find their application in available commercial systems. Of course, the market for IoT is still very small compared to standard applications, but with the further reduction in development costs and increasing reliability the market share is sure to grow. Intelligent or autonomous systems, that measure and control themselves are as well in development as decision supporting architectures, where a collective in-

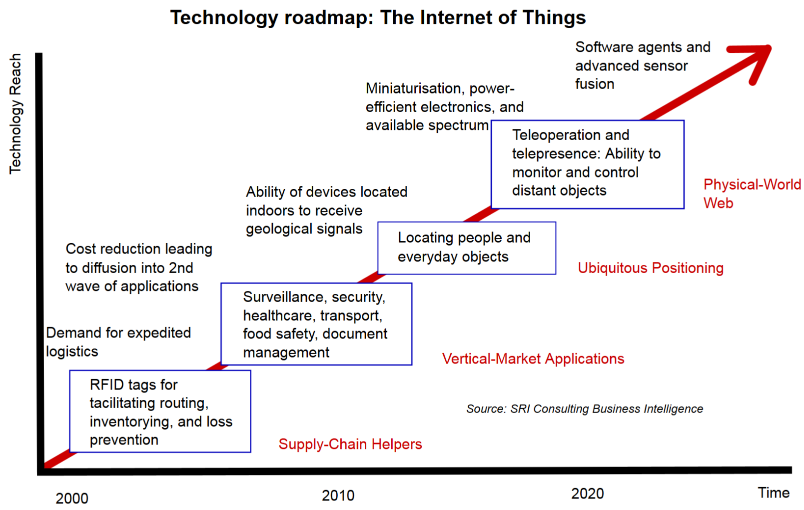

Figure 2.9 *The Roadmap for the development of the IoT technology [41].*

formation storage will be utilized to draw conclusions and support human decisions. These artificial intelligence systems are also relying on the Internet of Things idea, but will not be part of this thesis [41].

2.3.2 Available Platforms

Since the beginning of utilizing the IoT idea numerous different platform arose from different developing companies. Amongst them are big industry names like Microsoft, Google and Amazon. But also more specialized platforms have been created. One thing that all those platforms have in common is that they aim to make it easy for users to build applications that are designed for their use, with a set of tools provided. Generally, available platforms enable the user to build a piece of software that is able to receive data from a remote device, store it on a server and use it to display information about it on a graphical interface, which also has been designed with the platform.

Most of the available platforms focus on industrial applications. Unfortunately, there was no platform to be found that concentrates solemnly on tele-medical applications. The common platforms, like Intel, ThingWorx or Kaa, however, only offer the possibility to build tele-medicine architectures [42, 43, 44].

ThingWorx

One of the biggest providers, apart from the industry giants, is PTC Inc. with it's IoT platform ThingWorx. This is a java based, apache server sited running application, which allows the user to create his own objects, classes and, lastly, MashUps. MashUps are the graphical interfaces, that can be created from the given ThingWorx toolbox. The user creates the interface by drag-and-drop of the elements that are available and then connects the object, class or event that triggers a change in the interface. Currently ThingWory is available in version 6.6. A marketplace is offering a very large add-ons for the platform, to for instance integrate the MQTT (Message Queuing Telemetry Transport) connectivity protocol enabling machine to machine messaging. To run a ThingWorx application a server must be provided, that runs Apache and the Jave Runtime Engine [43].

The backbone of the platform is the composer, which is the interface for developers. It allows the creation of the different entities, alarms, users, usergroups. In figure 2.10 the composer is shown in a properties tab for defining values [43].

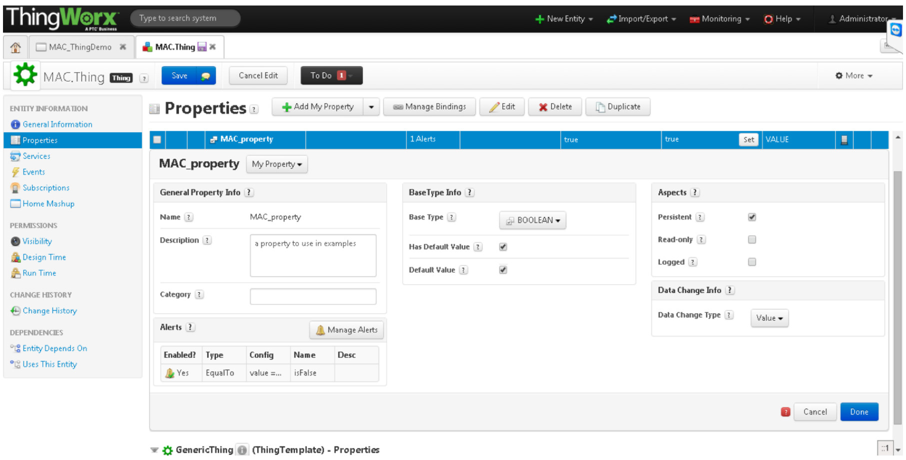

Figure 2.10 *The Composer is the developer platform for ThingWorx [43].*

It is possible to not only define the objects in this platform, but also certain triggers, for alarms, which is an important aspect when considering a tele-medical application. A large disadvantage at the moment of the creation of this thesis is that there is no mobile application builder introduced yet. However, it's said to be released in the summer of 2016. This would enable building applications not only for large screen devices but also for mobile phones [43].

Opposite to the other two introduced platforms, ThingWorx is not free for development. Instead, different packages can be bought, where the price is depending on the amount of service that is included in the package.

Amazon Web Services IoT

One of the biggest providers of online services also offers a platform to develop Internet of Things applications. Amazon Web Services (AWS) IoT offers again the functionality to bind internet-capable devices into an architecture and control their stream of data from or towards that device [45].

Again, user profiles and user groups can be defined that can access different parts of the built applications. In the review of this thesis it was not checked, how complicated the application builder actually is.

Other than the other two platform AWS offers also a wide range of other online products that enhance the capabilities of the IoT platform [45]. However, it seems not to be as flexible as the other two, concerning the integration of different messaging protocols.

The AWS IoT offers a unique feature: device shadows. The last known status of a device is always saved to the database. Those shadows can be used for the application development as stand ins for a device. Also, they can be used as a control value, to set the device to a certain state the next time it connects to the internet [45].

The IoT platform is free for trial and can be used up to one year, still server costs are not avoidable.

Kaa

Kaa is a relatively young, but open source development platform. It is provided from CyberVision and again poses as multi purpose platform for end-to-end solutions. Opposite to the other two introduced platforms, Kaa, is not intended for large scale applications, despite claiming to handle those as well. It also is Java based, but can handle C and C++ Software Development Kits (SDK)[44].

Kaa is available as standalone download for local servers, or can be deployed directly on AWS servers for free. An advantage of Kaa is the possibility to connect any already available, wearable device to the intended application and use its data for analysis.

2.4 Biosecurity

Nowadays, a lot medical devices are connected to a network, creating an interface between the hospitals, patients and medical device manufacturers. This digitized network makes medical devices vulnerable to third party interventions, leading to breach of doctor-patient confidentiality by unauthorized access or hacking. These risks raise the question of information and network security of all medical devices including patient monitors, insulin pumps, ventilators, infusion pumps, imaging modalities and pacemakers [46].

Since 1960s, the Food and Drug Administration (FDA) has considered some unintentional cybersecurity risks, which include the possible interference of radio signals or electromagnetic fields with implanted medical devices. Consequently, currently FDA and manufacturers warn the customers on these matters. However, as it was noted by Government Accountability Office (GAO), intentional threats to certain medical devices, specifically active implantable medical devices with close range communication such as Near Field Communication (NFC) or Bluetooth.

In a report, published in 2012, GAO urges the FDA to consider the information security for certain types of medical devices such as defibrillators and insulin pumps.[47] Since then, the FDA has become aware of the importance of cybersecurity risks and incidents. In June 2013, the FDA published an alert addressing to hospital networks and medical device manufacturers to point out the important aspects, risks, risk management and possible solutions [48].

The current program of the FDA is assessing the security of medical devices. It requires manufacturers to "assure their customers (for example patients, insured individuals, providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected" [2] [49]. Despite of this program, there is no specific guidance

[2] Department of Health and Human Services, "Health Insurance Reform: Security Standards; Final Rule," Tech. Rep. 34, 2003. [Online]. Available: http://federalregister.gov/a/03-3877

or requirement imposed by FDA, thus leading to medical devices varying widely in their safety features [50].

2.4.1 Cybersecurity for medical devices

Information or cybersecurity consists of data protection, services, systems and communications and controlling the risks against them by administrative, technical or other measures [51]. Cybersecurity in general consists of three security objectives:

- **Availability** - System must always respond according to its specification and design
- **Confidentiality** - Data can only be known by intended parties
- **Integrity** - Data cannot be altered without being detected and all systems affecting patient treatment must not be altered without patient's knowledge.
- **Authentication** - Only authorized parties should be able to act as a trusted user of the system
- **Authorization** - Actions of certain authorized parties have to be verified before implemented.

For Industrial Control Systems, to which also many medical devices belong, this is also the priority order of these security objectives. Availability means that the information is available to all authorized entities when they need it. Integrity of data on the other hand stands for unchanged information, which is accurate and has not been tampered. Confidentiality requires that the information is not revealed to unauthorized entities. Sometimes also authentication, meaning that the user has been recognized corresponding some identity in the system, is attached to the definition of cybersecurity [51].

In order to authenticate a user of an information system a login procedure is used. This identifies the user, which has been provided with a unique user name and password for that specific system. In figure 2.11 a standard login flow graphic is displayed. This flow is basic to any web service or information system, which utilizes different users. This is needed in order to either secure data from intruders, or to separate the data users have access to [52].

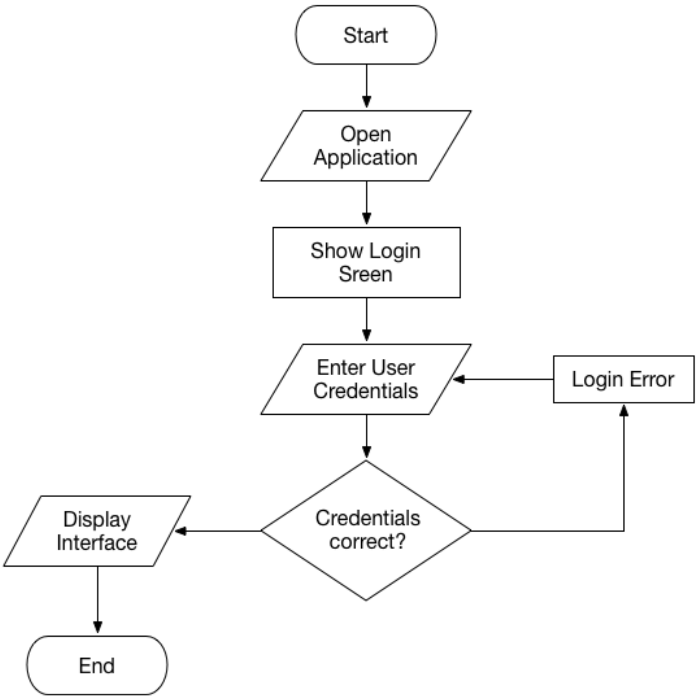

Figure 2.11 *The basic authentification process requires user interactions and displays different screens. After [52].*

Data integrity is also important in medical device context. If, for instance, monitoring device gives wrong information to the doctors, it can lead to improper treatment and cause large risk for the patient. Data from the device should be reasonable, accurate and fit for its purpose. Thus, data integrity is important for safety and utility reasons. In addition to be able to produce accurate and relevant data, medical devices should be tamper proof in order to preserve the data integrity [53].

Confidentiality and privacy are another important concern in medical device context, because many devices can contain sensitive information. It is possible, that a patient does not want any other person to know he or she carries an implantable medical device. Thus, unauthorized persons should not be able to determine whether a person carries a medical device nor what ID it has. Therefore, the device-type, device ID, measurements and any other information regarding to patient should not be readable from the device by unauthorized persons [53].

On the other hand, only authorized persons should be able to modify device settings and, the user should not be able to accidentally increase the medicine doses. This means that devices must be able to authenticate users and possibly use different roles for different users. In terms of medical devices this often means the general access to the device handling has to be restricted [53].

The 'International Electrotechnical Commission (IEC) 62304 Medical device software software life cycle processes standard' provides a framework for safe design of medical device software. In practice, companies producing medical device software must design their quality systems to implement this standard, otherwise it would be difficult for the software manufacturer to fulfill the regulations for medical device software. The IEC 62304 mainly describes the steps and guidelines to produce software that fulfill the regulations called for in the document [54].

2.5 Standardization of Digital Medical Records

Standardization in medical records is mainly used to support patient care. The general drive to digitize medical records is aimed to improve this support even more. A general problem with the process is that a standard has to be found which can be applied to older, paper records, in order to make them comparable and compatible. Standardization means to structure the records in order to bring direct benefits to the patient and the care giver [55]. There are different types od standards in medical records: data standards and terminology standards [54].

2.5.1 Standardization

Data standards provide consistent meaning to data shared among different information systems, programs, and agencies throughout a product's life cycle. These include representation, format, definition, structuring, tagging, transmission, manipulation, use, and management of data [54]. Terminology standards control terms and definitions used in submissions to the FDA. They are often used in combination with a data standard to aid in exchange and interpretation of data. The purpose of these standards is to:

- Maximise patient safety and quality of care
- Support professional best practice
- Assist compliance with Information Governance and NHS Litigation Authority (CNST) Standards

Unfortunately, there is no general map of which standards are needed in healthcare. Currently, standard development is driven by implementation needs and by specific interest of groups (companies, organizations) or individuals. There is only few government based standardization approaches in the world. Again, those standards are limited to the countries' borders and are not internationally compatible. It is clear that the issues identified in the development of standards have an impact on the adoption, conformance and compliance in such a diverse range of standards. The fragmentation of the developments rises difficulties in harmonization and terminology which inevitably has an impact on compliance. Furthermore, there are more issues relating to conformance and compliance which cross over from health software to mobile applications and medical devices.

2.5.2 Available Standards

Right now there are several standardization approaches in the world, that aim to unite companies and governments into one level. In Europe, especially the Finnish Kanta system and the German G1 act for standardization of medical record keeping are to be named. Both systems have the goal that the medical records are saved centrally, in a secure, country located server. In order to be able to write data from any office within these countries, a standard method of patient identification and terminology has been found. Other than those government based standardization approaches, there are also organizations, which try to establish a standard that can be applied in medical applications. The most prominent one is Health Level Seven (HL7), as an internationally operating organization.

Germany - G1

After years of serveral insurance companies in Germany, the act finally enforced that each individual is assigned one general ID number, that will not change, even if the insurance company is changed. This way it is ensured that recorded medical data and associated records, like prescriptions, can be transfered securely and compatible to the new insurance. Furthermore, recorded data will be available to medical professionals from the centralized server. This needs, however, more effort and time, since the saving of sensitive data on one single location is (still) prohibited by German law.

Finland - Kanta

The Finnish Kanta medical database is aiming for a similar approach: centralizing the records, in order to keep personnel easy up to date on the patients history. With the deployment of ePrescription in 2015 a step towards the future has been made. Figure 2.12 shows that an interoperability of subsystems will be enabled.

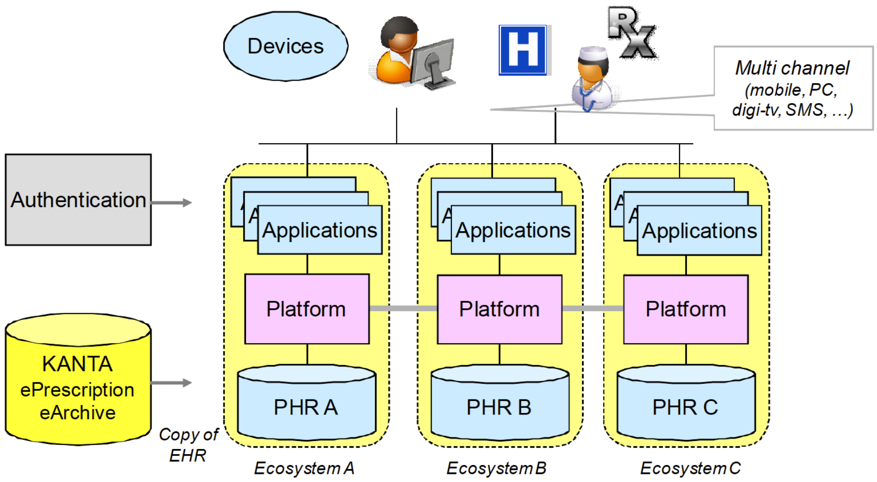

Figure 2.12 Kanta is the Finnish medical database [56].

International - Health Level Seven

Health Level Seven (HL7) is an international operating organization with the aim to provide standard regulations for medical record keeping. The general goal is to ensure interoperability between systems and care providing organizations. As other standardization committees HL7 strives to provide a data and terminology standardization. Lately, HL7 is also focusing on the implementation of mobile health (mHealth) records and Fast Health Interoperability Resources (FHIR). The latter introduced a simplified platform for medical device and software producers to implement the HL7 standards in newly developed products [57].

Over the course of 30 years, several versions of electronic medical record keeping standards were published. Generally, HL7 standards are now divided into reference categories [58]:

- **Primary Standards** - Most popular standards integral for system integrations, interoperability and compliance.
- **Foundational Standards** - Fundamental tools and building blocks used to build the standards
- **Clinical and Administrative Domains** - Messaging and document standards for clinical specialties
- **EHR Profiles** - Functional models and profiles
- **Implementation Guides** - Support documents and material
- **Rules and References** - Technical specifications, programming structures and guidelines for software and standards development.
- **Education & Awareness** - Resources and tools for understanding and adoption of HL7 standards.

3. DESCRIPTION OF THE ARCHITECTURE

The aim of this thesis is to describe a base for an architecture, which can be used to build an proof-of-concept prototype system. This system should generally include all the major described components in order to measure and evaluate the ECG and EIP signal of a patient using a wearable shirt that incorporates a hybrid flexible, printed electronic layout. The Architecture shall be divided into three different sections, also shown in figure 3.1.

- The Patient Site (blue)
- The Server Site (green)
- The User Site (red)

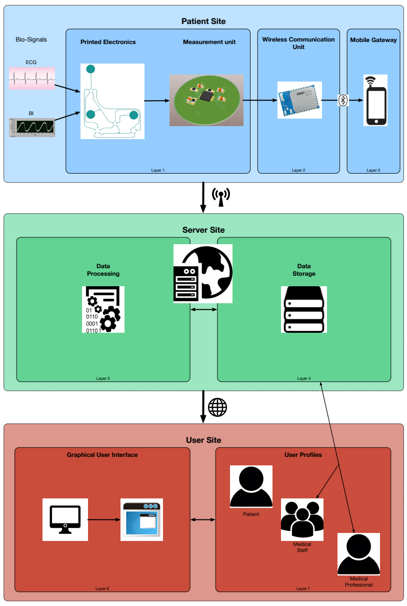

Figure 3.1 *The complete Architecture, which contains all 7 Layers of a IoT system. Check Appendix A at page 54 for a larger image. With images from [20, 59].*

As visible in figure 3.1 the differentiation is based on the layers of an Internet of Things architecture (see chapter 2.3.1, p. 16). The physical, connectivity and Edge computing layers are represented by the Patient site of the architecture. The printed electronics together with the measurement unit build the physical layer. The connectivity (Layer 2) is ensured via the wireless communication unit, which utilizes the BLE112 Smart Bluetooth module by Bluegiga. Lastly, the edge computing is carried out by the connected smart phone, which is described in the mobile gateway section.

Furthermore, the Server site (see chapter 3.2) represents the next two layers of an architecture for IoT based applications. The recorded data is collected on a Finnish located server (Layer 4: Data Accumulation) and is then processed and saved in a database format suitable for the utilized IoT platform Thingworx (Layer 5: Data Abstraction).

The last two layers of the IoT based architecture are found in the User site. As there will be suggestions for a graphical user interface, the sixth layer is covered. The seventh level is represented in the user profiles section, where one can understand that different profiles are needed in order to access the data in different ways.

3.1 The Patient Site

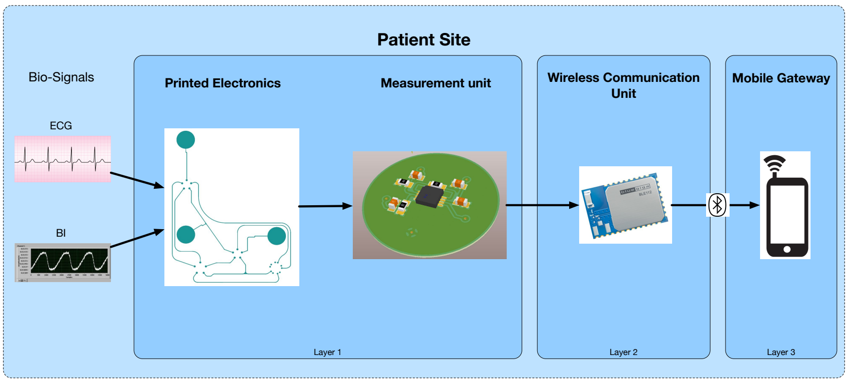

Figure *3.2 The structure of the patient site includes various active electronic components and a bluetooth connection. For a larger image, in relation to the other sites, check Appendix A at page 54. With images from [20, 59].*

This part of the described architecture deals with the physical devices that are connected to the patient, or used to record the bio-signals. Therefore, this section will deal with the printed electronics and their layout, the measurement unit, which incorporates the Texas Instruments ADS 1292R and includes a power source, the wireless communication unit; represented by the Bluegiga BLE112 module; and lastly the mobile gateway, which communicates and sends the acquired data to a server located in Finland. Figure 3.2 depicts a short overview of the patient sites' components and the signal travel.

The transportation of the data between the devices is planned to happen as in shown in figure 3.3. Tha data recorded by the measurement unit is packed into packages of a few kilobytes size and sent to the mobile gateway. The mobile gateway unpacks these and repacks bigger packages in order to send them to the server via GPRS.

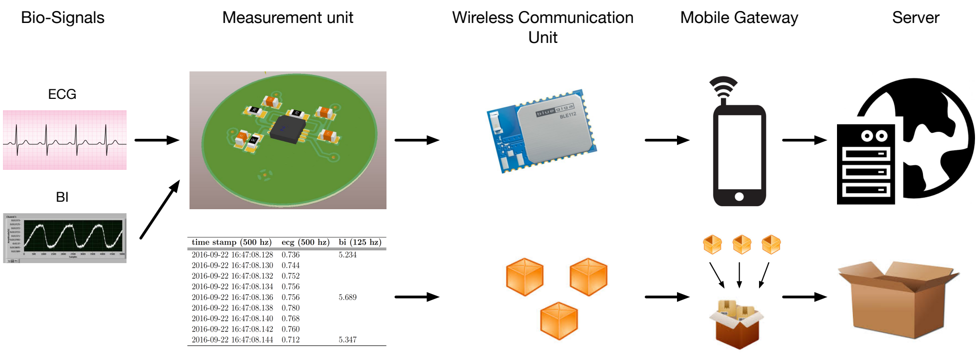

Figure 3.3 *The data is recorded and stored in a data format Between the Bluetooth connected devices small packages are sent, whereas the mobile gateway will unpack the packages and repack larger ones in order to send them to the server. With images from [20, 59].*

This method is used in order to reduce the connection time between the mobile gateway and the local Base Station Transceiver. This saves power on the gateway, because no permanent sending is happening.

3.1.1 Printed Electronics

The electronics that connect the electrodes, which themselves are also part of the printed, flexible layout, with the two other units that are incorporated into the t-shirt. The electronics that are printed with screen printing onto a TPU substrate. The classic rigid circuit board built measurement and communication unit are then attached onto the connector points of the layout. Finally, the substrate is laminated onto the fabric face down to avoid interferences and distortions through the patients body. The electrodes, however, are turned up-side-down, in order to provide contact with the skin.

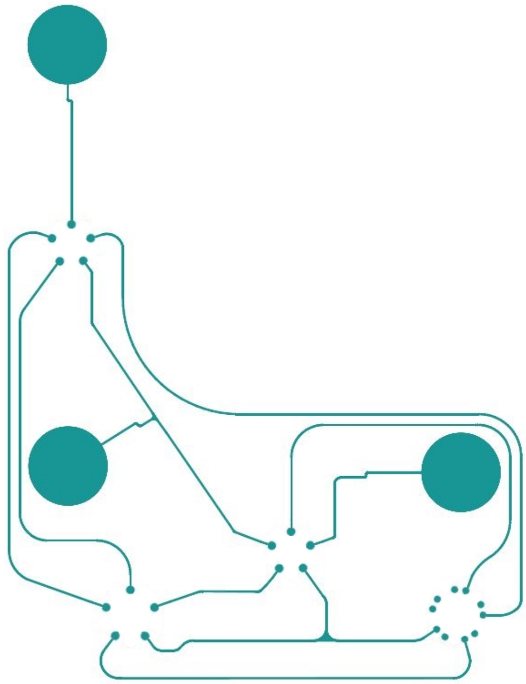

Figure 3.4 *The design of the printed electronics utilized in the architecture. The shown design is not the final version, as this contains confidential parts and cannot be used in public work at the moment.*

Figure 3.4 shows a version of the screen printed electronics used in the concept. As the final design contains confidential parts, it cannot be used in public work at the moment. The shown layout still provides a good idea of what the electronics will look like. The dimensions of the layout are: 164 mm by 215 mm. The larger areas are the electrodes that are in contact with the patients skin and used to record the ECG and the bio-impedance. Their diameter is 25 mm.

The smaller star like structures are the connector areas, where the measurement unit, the wireless communication unit and the power source will be placed. The external units will be connected with a bio-compatible, conductive glue that has to withstand washing, as the t-shirt, has to be cleaned. As this is a proof-of-concept work, the design should at least with-stand hand washing.

3.1.2 Measurement Unit

The measurement unit, which is a classic rigid substrate ciruit board with surface mounted resistors and capacities, will incorporate the Texas Instruments Inc. (TI) ECG and bio-impedance measurement chip ADS1292R [60]. As for the proof-of concept system a non-rechargeable coin cell battery will power the whole application. The power source will be included on another external module, which will not be described closer in this work. Currently, Katariina Tuohimäki is working on a Master Thesis to closer investigate the ADS1292R and its incorporation in the architecture.

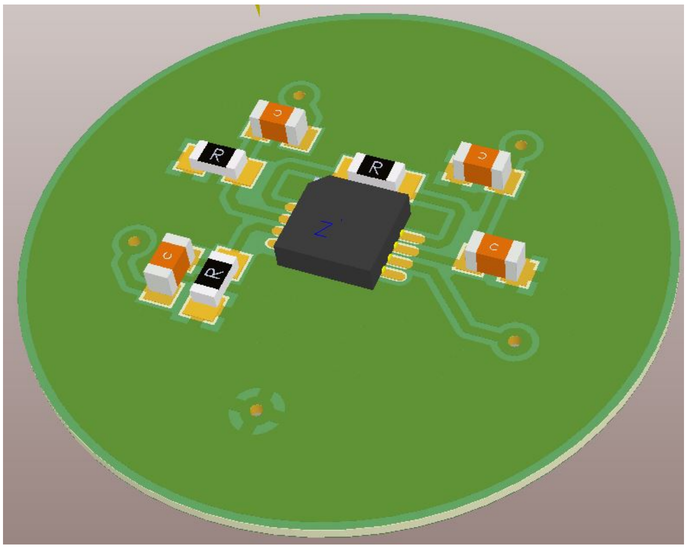

Figure 3.5 *A rendered version of the printed circuit board (PCB) that incorporates the TI ADS1292R and other passive components.*

Figure 3.5 shows a rendered version of the (rigid) printed circuit board (PCB) that incorporates the ADS1292R and needed passive components. The diameter of this board is 19 mm, which is about as large as a 10 Eurocent coin. All of the used components are surface mounted to save space, which is important for the miniaturization in these applications. After the mounting of the components the whole layout can be polymer coated, or placed in encasing in order to provide protection of the sensitive electronics.

The TI ADS1292R is a 3-channel 24-bit analog-to-digital converter (ADC), specifically designed for the utilization in medical applications. It is equipped with a built in functionality for ECG and respiratory BI measurements. It needs a supply voltage between 2.7 and 5.25 V. The chip uses only 335 μW per channel that is used in the application, totaling at a 1.005 mW for the whole application. This low energy consumption makes it the choice for this architecture, because it enables the planned long term functionality of the system on a small power source. Also included in the chip is a 50/60Hz filter to exclude distortions through the general land line AC. The chip itself measures 5 x 5 mm including the leads and is advised to be operated between -40 and 85 °C [60]. Furthermore, the chip adds another functionality to the system, as it incorporates a three dimensional accelerometer.

The ECG measurements are to be done with the standard 500 Hz sampling frequency, as the BI measurement is run at 125 Hz. These frequencies should suffice for the planned data processing and provide a high-enough resolution. As of now, there is no decision on the sampling rate of the accelerometer values. Given the values of ECG and BI, a multiple of 125 Hz would be most sensible. The ECG sampling rate can even be lowered to 250 Hz, in order to not produce too much data. This is another crucial aspect of a mobile monitoring application in order to save energy, due to fewer transmissions, because of less data.

3.1.3 Wireless Communication Unit

The wireless communication unit utilizes Bluetooth Low Energy. The modules' center is the Texas Instruments CC2540 chip that is incorporated in the Bluegiga BLE112 Bluetooth Smart Module. Using an low-energy module is essential in a mobile longterm measurement system, as stated earlier. In figure 3.6 the wireless communication unit is shown in total, in the middle the BLE112 module by Bluegiga [61, 59].

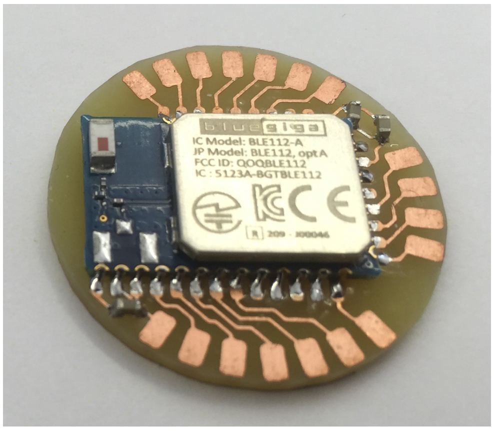

Figure 3.6 *A low energy Bluetooth module with compact measurements is soldered onto a PCB.*

The BLE112 module measures 18.10 x 12.05 x 2.3 mm, which makes it a very fitting part of the system, where small parts are needed in order to not discomfort the patient. The very low current consumption of 36 mA in stand-by and 0.4 μA while sending data made this module the choice for the testing system, as the provided energy has to be mobile, and therefore small, as possible [61]. The module is incorporated in a waterproof and bio-compatible shell that includes conductive connectors on the bottom side which are connected to the printed electronics with a conductive glue. The finished module measures about 25mm in diameter (about the size of a 2 Euro coin).

The BLE112 has an integrated micro processor, which makes it possible that the recorded data is collected and packed into a ASCII table format that can be read by the mobile gateway unit. The table should contain following information:

- Time stamp
- ECG lead II measurement values
- Bio-impedance measurement values

The composition of the table in ASCII format should lead to a overview that looks like table 3.1. The time stamp has the format YYYY-MM-DD HH:MM:SS:mSmSmS in order to control the correct sampling of the signals. The two bio-signal should be read and saved as accurate as necessary and as small as possible, in order to save transfer time. The accelerometer values for each axis will also be included into this table in the same manner on the right hand side.

3.1.4 Mobile Gateway

The mobile Gateway will be (as well as the server structures) provided by Elisa Oy. In the case of this architecture it is a smart phone running Android OS in a not further stated version. The mobile phone is connected via Bluetooth Low-Energy to the wireless communication unit and receives the measured data as packages in a defined interval. This is to reduce the amount of energy used with these connections: package sending is more energy efficient than a continuous data stream. The smaller the defined interval is, the smaller the sent packages can be.

Table 3.1 Example table that should be created by the BLE112 before sending the data to mobile gateway

time stamp (500 hz)	ecg (500 hz)	bi (125 hz)
2016-09-22 16:47:08.128	0.736	5.234
2016-09-22 16:47:08.130	0.744	
2016-09-22 16:47:08.132	0.752	
2016-09-22 16:47:08.134	0.756	
2016-09-22 16:47:08.136	0.756	5.689
2016-09-22 16:47:08.138	0.780	
2016-09-22 16:47:08.140	0.768	
2016-09-22 16:47:08.142	0.760	
2016-09-22 16:47:08.144	0.712	5.347

An application in the background regulates the connection with the communication unit. The recieved packages are unpacked into a data file that contains the same information, but recombined. This application also sends newly packed, bigger packages (chucks) of data via the GPRS connection to a server.

3.2 The Server Site

After the data has been acquired, it will be sent from the mobile gate way to the server. This represents another major part of the architecture. On the server data processing and analysis will happen, as well as data storage. For the aimed proof-of-concept system, the storage will be reduced to a minimum, that can be used for testing purposes. In Chapter 4 possible and necessary enhancements will be suggested, which are focusing on the reduction of processing power.

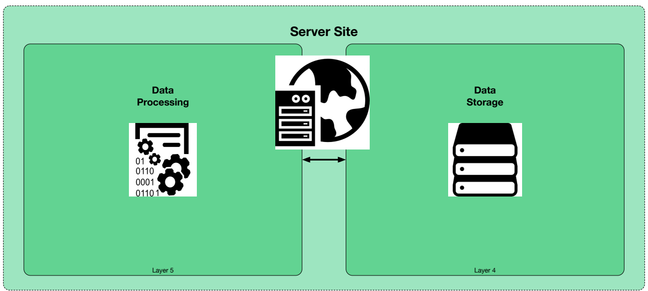

Figure 3.7 The server has two general functions in the architecture: data processing and data storage. For a larger image, in relation to the other sites, check Appendix A at page 54

In the following sections suggestions for a staged storage are made and the planned data processing aims are described. For the DISSE project Elisa Oy will provide the needed servers.

3.2.1 Data Processing and Analysis

With the data arrived on the server the processing of it has to happen in order to obtain crucial parameters for the patient's status. Very often those are a huge number of parameters, especially for ECG measurements. However, to reduce the processing power, the most common and useful ones are selected for the proof-of-concept system. Later more complex and processing intensive algorithms can be added. At the moment of writing of this thesis Shadi Mahdiani is investigating these processes and their function closer. She will present the results of this in her own Master Thesis, created in Tampere University of Technology.

Most important before any kind of parameter search is a filtering method that excludes the parts of the signals that are not usable for analysis. This means that at least bandpass filtering and other noise reduction techniques are applied on the signal before further processing.

Important to any ECG analysis is the detection of the R-peak. Different methods for that are in the discussion momentarily and no final choice has yet been made for the prototype system. Aiming for further anomalies that can be detected in the ECG, an ectopic beat detection method is also in development. With those methods, parameters like: Heart Rate or its variability are calculated and give a deeper insight in the status of the patient. Not only the R-peak is important for the analysis of the heart condition, but also other parts of the ECG can be used for further investigation. For example, the ST-segment can give insights about myocardial infarction or coronary ischemia depending on its elevation or slope.

As for the EIP, the most common used method, again, is the peak detection. With the detected peaks in the signal the easiest parameter to determine is the breathing frequency. As well, with the amplitude of the signal, it can be measured how deep the patient is actually breathing and whether or not he/she might be under supplied with oxygen.

3.2.2 Data Storage

Generally spoken, the recorded data will be secured first on the storage available on the server for further processing. A staged stored system is, however, needed, since not all the data can be kept. Not neglecting 'unimportant' data leads to a mass of accumulated records, that not only are highly unlikely to be useful, but also slow down the processing power of the server.

In order to reduce the amounts of stored data the, mentioned, staged system is introduced. Staged means in this case that older data is compressed by averaging the values of:

- one hour for the last 48 hours
- one day for the last 14 days
- one week for the last 3 months
- one month for the last 2 years

Of course, to realize this an algorithm has to scan and compress said storage data. This will require more computational power, but is essential to not slow down the other processes. The compressing can be done once per hour to keep the processing load to a minimum. This will enable the medical personnel to review a trend of the patients status within a reasonable time frame for most conditions, yet save storage space.

If found in the prototype testing phase that those compressed values are too low or too high they are able to be altered for further testing. Again, different medical conditions can ask for appropriate settings.

3.3 The User Site

The user site is represented by the graphical interface on which the users can view the visualized data and the user profiles. As opposite to the patient site, the below mentioned patient profile has nothing to do with the hardware. This section focuses purely on the user profiles, which are used to access the data which is stored on the

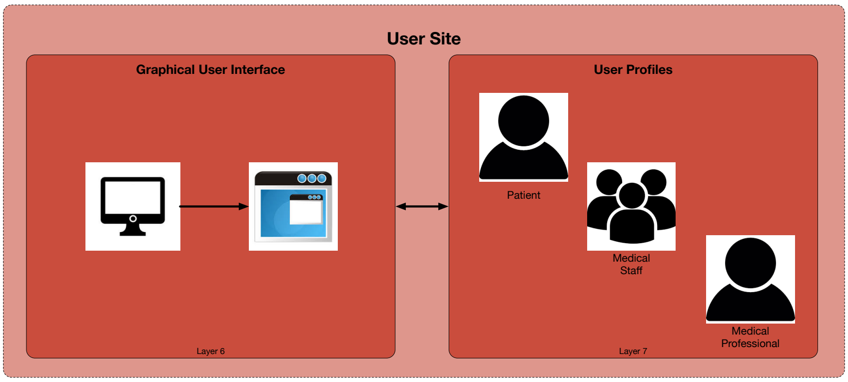

Figure 3.8 *The user site is represented by the graphical interface for visualized data and the user profiles. For a larger image, in relation to the other sites, check Appendix A at page 54*

server, and the visualization of said data in a graphical user interface. Figure 3.2 shows those two parts of this sector in the architecture.

Because this thesis is here to describe the architecture and not to provide the functional prototype, only suggestions are made in the following sections. For the design of a graphical interface the help of a professional industrial designer might be advised. The described procedures here, normally happen in the earlier described IoT platform. There profiles can be created that allow only certain access to defined user groups, so called user profiles or roles. As well the graphical interface is built in these platforms.

3.3.1 User Profiles

IoT Platforms always allow to create different user groups with distinct access rights. This should be utilized in the architecture as to define which user group has access to which part of the data. In general, there need to be three user profiles defined:

1. Patient Profile
2. Medical Personnnel Profile
3. Medical Professional Profile

Each of which bares the access rights suitable for the individual group of users. In the following section user rights are discussed in more detail and the possibilities of each profile are shown closely. Each profile has its own reading and writing access rights.

The profiles are secured with passwords for each created user account. The accounts have different roles attached to them, which are defined at the accounts creation through a system administrator.

Patient Profile

The patient profile enables the patient to see his/her own data. This profile is mainly used for self control. It is intended to just present the data history, so that he/she can check, when interested.

The patient may check on the provided smart phone via the application or the browser based interface after a login process. Since the interface is browser based a standard computer could also be used to login and view the information. However, this profile is not able to access all information stored on the server. Generally, the patient can view his current heart rate and respiration rate. Maybe a trend overview of the last days can be included.

Opposite to the other profiles the patient one is not able to change or add any medical important information. However, it is crucial to give the opportunity to patients to add feedback or information into their data-file. This not only gives a feeling of security and importance towards the patient, but also can provide information to the personnel and doctors.

Medical Personnel Profile

Usually the personnel having most contact with the patient are nurses. To provide important information about the patients' status this user profile gives all measured and calculated parameters.

Additional to access to the current status, the personnel is able to access the medical history of the patient, for as long as he has been using the wearable tele-medicine system. A possible interface for the access is described a little later.

As well as the patient, the personnel is able to add information about the status. However, this profile is able to annotate the data in order to mark incidents or important events, which should be double checked by the medical professional.

Medical Professional Profile

The difference between the personnel and the medical professional is that the latter is able to add diagnostic information to the patients' data file. Otherwise the general functionality between these profiles are the same. To provide more information for the doctors, this profile is also able to access the whole medical history of the patient. For this functionality a standardized medical record keeping is necessary, in order to view it correctly.

3.3.2 Graphical User Interface - GUI

Generally, at least two different interfaces are needed: One for a mobile platform and one for a computer based platform with a larger screen area. This is important in order to ensure an appealing interface for users accessing the data from different platforms. In figure 3.9 ideas for those GUIs are presented.

Figure 3.9 *The Graphical User interface should be accessible on different platforms, therefore two versions are needed: A) Desktop Version and B) Mobile Version.*

Where the mobile interface should only contain basic information, about the momentary status, the desktop interface gives access to the full picture.

Visible in the mobile interface are the current heart rate (calculated on the server for the e.g. last 5 minutes), the breathing frequency, total steps for the calender day and a overview of the heart rate trend in the last 24 hours. A comment field provides the possibility to add information.

On the other side, the desktop application ((A) in figure 3.9) provides more information about the patient. After a login and patient selection, a panel shows the basic information about the patient that have been entered at acceptance. Again, current heart rate and respiratory rate show the lastest status. Trend lines and history of chosen parameters can be displayed as well. Logos at the bottom corner mark the developer, the DISSE project and their partners. A patient profile picture might be used for easier identification. A field with the latest alarms shows all recent alarms applicable for that patient.

The mobile application ((B) in figure 3.9) is mainly intended for short overview and can be used by all three user profiles. However, the desktop application is intended only for usage by the medical personnel and doctors. On start of the applications the user is asked for his/her account credentials, on the entering of which the main screen is displayed. Depending on the profile, the person has different viewing or writing permissions, as described earlier.

4. DISCUSSION

4.1 Design Flaws and Problems

Starting with more general flaws this chapter will also discuss more specific ones that the individual parts can have. The system as describe above is designed to be able to assemble a proof-of-concept prototype containing all the elements. It has been designed with the future in mind, so that modular part can be added to increase the architectures' capabilities.

As possible flaw of any mobile system the batteries have to be named. Every part of an electrical measurement system has to be provided with electricity and is useless if the batteries run out. Therefore, any alterations of the architecture has to be made with the power consumption in mind. All the single devices have constantly be monitored to not run out of battery. They have to be charged or the batteries have to be replaced, which produces a new challenge on how to design a user friendly and reliable charging system.

This system is designed with the freedom from cables to make the usage more comfortable for the patient and the medical personnel. This leads to the problems that wireless technologies still possess. The Bluetooth has only a short range where it can reliably transfer data between the devices. Therefore, it is a necessity that the patient has the mobile gateway always close by. In case of a smart phone the biggest problem might be that it can be forgotten, which makes this not only a technical, but also a human fault based, design flaw.

Looking at the wearable piece of clothing that incorporates the printed electrodes; To produce any usable electrical bio-signal, the electrodes need to remain in constant contact with the patients' skin, since the observed signal changes depending on the electrodes' locations. This cannot be ensured with the idea that this system is designed with. The step away from attached electrodes provides most likely the hardest challenge in the realization of this project. To ensure a relatively good contact with the skin and also fewer detachments, the shirt has to be quite tight fitting, this can make it uncomfortable to wear. Motion artifacts can cause a problem for the signal processing and analysis part that have to ensure correct filtering and treatment of such distortions. Additionally the shirt has to be able to be washed at high temperatures to ensure aseptic status.

As for this project the ThingWorx IoT platform by PTC was intended, but turned out to be far too complex for actual use in the prototype. Instead more reasearch has to be put into this. Candidates for the applicable platforms should be the open source structure of Kaa or the generally free Amazon Web Services. Those will not include the server storage or processing power, but neither does Thingworx. As for this project Elisa Oy will provide the needed servers.

Also, none of the mentioned IoT platforms has a Matlab compatibility, which is somewhat important for the DISSE project, since the data processing is done in said program. That means that the data has to be collected, exported, evaluated and imported back into the platform. This completely, will disable a 'real-time' functionality of any IoT platform.

4.2 Future Outlook

As the thesis thrives to provide the best possible base for a telemedicine system that utilizes IoT platform and is expandable for future use, the following parts will focus on what to include in a further development.

4.2.1 Software Enhancing

Adding more user profiles. For example the relatives of the patient should be able to check on him via a 'visitors/relatives/family' user profile and be able to see latest general changes. Also a face-to-face video conference with the patient and the doctor via a secure communication line could be included.

A very important part of the future system is the data storage of the medical records. Not only has the data format already to be considered now in the development, but also it is necessary to face future developments in regard to formats of medical record keeping. The system as it is right now may store some essential information, but for further development a standard has to be integrated in the architecture.

The most important next step for the software development, however, will be to implement an alarm system, which already operates on the gateway device level. In case of heart failure, breathing complications or a sudden fall, an alarm has to be triggered right on the gateway, without sending the data first to the server to be analyzed. To do that general, very specific data processing algorithms already have to be implemented into the gateway software.

4.2.2 Hardware Enhancing

Not only the software has to be considered when integrating more functions in the future, but especially the hardware part can be enhanced as well, more sensors can help assessing more data and give detailed information about the patients status.

Sensors

As far as the sensors go, there is basically limitless possibilities. Adding more physiological signals that can be directly recorded from the body is a matter of the utilization of the printed electronics and their connections. For example accelerometers can be used for the number of steps or the general movement, as in commercial available wearables. The motion data can be used to assess the physical activity of the patient.

An implemented Global Positioning System (GPS) module, or the location data from the smart phone can be used to locate the patient, in case he/she is outside of the facility, e.g. on a walk. This data could be used in case of emergencies to locate the patient and send an ambulance directly to the location, without waiting for a third party to call and ask for assistance.

Ambient sensoring can be introduced in a later stage. This means that more than just vital parameters are being monitored. Certain signals might just be usable for evaluation of the health stage of a patient. Incorporating a sensitive element in the fridge might allow to track the eating behavior of the patient.

Buffer Storage

To ensure a gap-less recording that enables more meaningful diagnostics, a buffer storage should be included into the architecture design. The buffer storage should be as large to keep recorded data from at least 24hours. This should be used to ensure that no data is lost during the longterm usage of the system.

5. CONCLUSION

It can be stated that the aim of this work, to describe the architecture for a proof-of-concept measurement system that utilizes IoT structures and printed electronics, has been achieved. With this, the motivation for creating a new approach to tele-medical systems can be satisfied. To support further improvement of the treatment landscape is just but one thing, someone can achieve to help people recover from their illnesses and unwell-being.

This work finds relevance in the surroundings of other described tele-medical architectures by incorporating a new aspect. The conceptual layer structure of an Internet of Things application, which was described by Cicso Systems can be modeled onto all parts of this architecture. This furthermore proves that basically any modern tele-medical system, which utilizes wearable technology, can be mapped onto this layer concept.

The biggest challenge in creating this work was the communication with all involved parties and introducing their needs and wants in this thesis. Nevertheless, the base framework for all DISSE researchers is now fully described and feedback already showed that it was very helpful for fellow researchers to find out what happens before or after their respective subproject. It was interesting to see that there is a general direction of development for government based medical record databases and a fair amount of consistency throughout European countries.

Lastly, a definitive remark can be made by stating that the future development of tele-medicine will definitely involve more wireless connected devices. Also, incorporating smart devices is a direction in which the technology heads. Furthermore, will the artificial intelligence find its way sooner or later into this sector of technology. With the innovation of startups, as well as the research done in major companies an interconnected health care system might not be too far.

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APPENDIX A - THE COMPLETE ARCHITECTURE

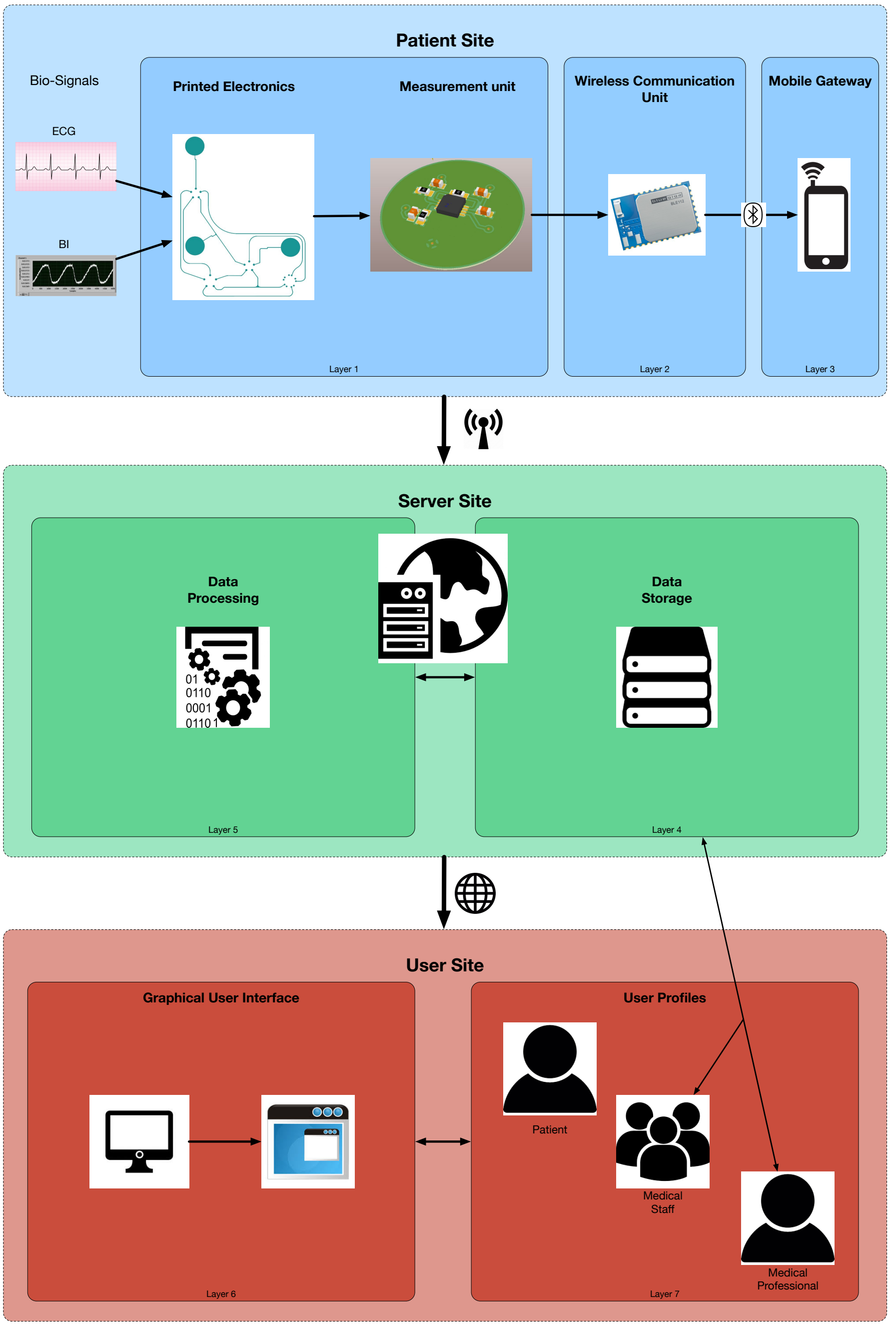

Figure 1 *The complete Architecture, which contains all 7 Layers of a IoT system. With images from [20, 59].*